



1642  
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re the Application of

Keith Willison, et al

Application No. 09/423,351

Filed: May 10, 2000

For: BINDING COMPLEXES

Examiner: Karen A. Canella

Group Art Unit: 1642

Response to Paper No. 15

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TRAVERSAL AND REQUEST FOR

RECONSIDERATION OF REQUIREMENT FOR RESTRICTION

A restriction requirement under 35 U.S.C. §121 was set forth in the Official Action dated May 19, 2003 in the above-identified patent application. It is the Examiner's position that claims 1-43 in the present application are drawn to three (3) patentably distinct invention which are as follows:

Group I, claims 1-19 and 31-37, is drawn to a method of identifying a binding member capable of occupying a substrate binding site on the CCT complex or part thereof (e.g. the CCT apical domain of claim 11) and to a method for screening for mimetics of the binding member of claim 20.

Group II, claims 20-30, 38, and 39, is drawn to a binding member capable of occupying a CCT substrate binding site (claim 20) and the CCT apical domain (claim 39), which is a substrate binding site for a binding member.

Group III, claims 40-43, is drawn to nucleic acid, vectors and host cells comprising the CCT apical domain of claim 39 (Group II).

Applicants respectfully submit that the restriction requirement set forth above is improper for failing to comply with the relevant provisions of the Manual of Patent Examination Procedures (M.P.E.P.).

It is submitted that the present Application is a national stage application of PCT/GB98/01485 under 35 U.S.C. §371. The present claims 1-43 have met the requirement of unity under PCT Rule 13. Specifically, the requirement of unity under PCT Rule 13 is fulfilled when a technical relationship involving one or more special technical features exists, the special technical features being those technical features that define a contribution which the claims, as a whole, make over the prior art (PCT Rule 13.2).

The Examiner has cited prior art documents WO 98/24909 and WO 93/25681, identified in the international search report as relevant to the claims 1-47 as originally published. Since publication, amendments to the claims have been made under Article 34.

WO 98/24909 is concerned with *E.coli* GroEL, a type I Chaperonin, whereas the present application is concerned with CCT, a type II Chaperonin. The substantial differences between GroEL and CCT are set forth on pages 2-3 of the present application. Inasmuch as WO 98/24909 is not concerned with methods of identifying CCT binding members, the CCT binding members themselves or the substrate binding site of the CCT apical domain or nucleic acid encoding the CCT apical domain, the Examiner's assertion that the disclosure in this application anticipates the claimed invention is erroneous on its face.

WO 93/25681 is concerned with Eukaryotic folding complexes. Again the claims have since been amended during IPE and limited to CCT apical domains having at least 80% homology with the amino acid sequence of D219 to N394 of CCT $\delta$ . Accordingly, it cannot be reasonably maintained that the present claims are lacking in novelty over the disclosure in WO 93/25681.

In terms of PCT Rule 13, Group I is directed to methods of identifying a binding member which will occupy a substrate

binding site of the CCT complex and to a method for screening for mimetics of binding members (of Group II). Group II is directed to the binding member itself and to the CCT apical domain substrate binding site of claim 39. Group III is directed to nucleic acid, vectors and host cells encoding or comprising a CCT substrate binding site to which the binding member of Groups I and II may bind.

None of the cited prior art discloses any such binding members, methods for their identification or screening or CCT substrate binding sites. This is confirmed by the International Preliminary Examination Report at Item V. These technical features of claims 1, 11, 31, 20 and 40-43, in particular, make a contribution, as a whole, over the prior art in the identification of CCT substrate binding sites enabling identification of the region of CCT protein substrates (BEP's) involved in binding prior to protein folding which provides for identification of binding members, including methods for doing so.

As there is a technical relationship between the claims by way of corresponding special technical features which, as a whole, define a contribution over the prior art, restriction under PCT Rule 13 is not proper.

Additionally, even if the present Application was filed as a U.S. application, the restriction requirement set forth in the Official Action is not proper under 35 U.S.C. §121.

Applicants respectfully submit that restriction under 35 U.S.C. §121 may only be required when "...two or more independent and distinct inventions are claimed in one application..." .

#### Independent

According to MPEP 802.01, "independent" means that "there is no disclosed relationship between the two or more subjects disclosed", that "... they are unconnected in design, operation,

or effect". An example provided is a "...process and apparatus incapable of being used in practicing the process".

Clearly, claim Groups I, II and III are not independent within this meaning. There is a clear relationship between the binding members of claims 20-30 and 38 and the methods for their identification of claims 1-19 and the method for screening for their mimetics of claims 31-37. The relationship between the binding member of claim 20 and the CCT apical domain of claim 39 is already established by the Examiner (Group II contains claims 20-30, 38 and 39). Further, there is a clear relationship between claims 40-43 and claim 39 in that claims 40-43 are in respect of nucleic acid sequences coding for the CCT apical domain of claim 34, or vectors comprising the nucleic acid, or host cells comprising the vector.

#### Distinct

In MPEP 802.01, the subjects considered as "distinct" are required to be patentable over each other. According to MPEP 808.02, in order to insist upon restriction, an Examiner must show by appropriate explanation one of:

- a) Separate classifications - the international search demonstrates this is not the case;
- b) Separate status in the art - no separation of subjects for inventive effort is evident; and
- c) Different field of search - again, the international search demonstrates this is not the case.

In this case, restriction under 35 USC 121 is not proper. The requirement for "independent and distinct" is not met. Inasmuch as search and examination of the entire application can be made without serious burden (MPEP 803), examination of claims 1-43 is requested.

There being no sound reasons for restriction under either PCT Rule 13 or 35 U.S.C. §121, the Examiner is requested to

withdraw or at the very least modify the present restriction requirement and examine claims 1-43 in a single patent application.

Whilst the restriction requirement is traversed, applicant provisionally elects Group I of the claims identified by the Examiner (i.e. claims 1-19, 31-37) for examination on the merits.

Early and favorable action on the merits of this application is respectfully solicited.

Respectfully submitted,

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